UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

OUITA CORLEY	)	
	)	
Plaintiff,	)	Civil Action No.
	)	
v.	)	_____
	)	
STRYKER ORTHOPAEDICS, A DIVISION OF STRYKER CORPORATION AND STRYKER SALES CORPORATION	)	
	)	
Defendants.	)	

COMPLAINT AND JURY DEMAND

Ouita Corley ("Plaintiff"), by and through the undersigned counsel, brings this complaint against Defendant, Stryker Orthopaedics, a Division of Stryker Corporation and Stryker Sales Corporation, and alleges as follows:

SUMMARY OF CASE

1. This is a personal injury/products liability action brought by Plaintiff against Defendant in regard to the design, testing, manufacturing, labeling, marketing and sale of the ShapeMatch Cutting Guide that was used to position a total knee replacement that was implanted in Plaintiff's body.

PARTIES

2. Plaintiff, Ouita Corley, is a citizen of the State of Louisiana and resides in Boyce, Rapides Parish, Louisiana. A substantial part of the events or omissions giving rise to Plaintiff's claim occurred in or near Lafayette, Lafayette Parish, Louisiana.

3. Defendant, Stryker Orthopaedics, a Division of Stryker Corporation and Stryker Sales Corporation, is a corporation organized and existing under the laws of Michigan, with its principal place of business in Kalamazoo, Michigan. Defendant does business throughout the United States, including in the State of Louisiana, as Stryker Sales Corporation. Defendant is registered to transact business within the State of Louisiana, and may be served with the summons and complaint through its registered agent, CT Corporation System, 5615 Corporate Blvd., Suite 400B, Baton Rouge, LA 70808.

4. Upon information and belief, at all times herein mentioned, the employees of Defendant, its subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendant, and at all times relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendant, such allocations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of Defendant committed, knew of, performed, authorized, ratified and/or directed such transaction on behalf of Defendant while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

6. Defendant is subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendant did (and does) business within the State of Louisiana, has had continuous and systematic contacts with the State of Louisiana, has consented to jurisdiction in the State of Louisiana, and/or has committed a tort in whole or in part in the State of Louisiana against Plaintiff as more fully set forth herein. On information and belief, Defendant also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

7. Venue is proper in United States District Court for the Western District of Louisiana pursuant to 28 U.S.C. § 1391, because: (a) Plaintiff resides in the Western District of Louisiana; (b) a substantial part of the events or omissions giving rise to the claim occurred in the Western District of Louisiana; and (c) Defendant has sufficient contacts within the Western District of Louisiana to subject it to personal jurisdiction. Defendant transacted business in or directed at Louisiana and its citizens and by commission of tortuous acts that caused injury in Louisiana and by purposefully availing itself of the benefits of Louisiana law by regular, continuous and systematic contacts with Louisiana.

THE STRYKER SHAPEMATCH CUTTING GUIDE

8. In May, 2011, Defendant received EPA clearance for its ShapeMatch Cutting Guides for use with the company's Triathalon Total Knee System.

9. The Shape Match Cutting Guides are single use, disposable cutting guides. They are intended to be used as surgical instrumentation to assist in the positioning of total knee replacement (orthoplasty) components in guiding the marking of bone before cutting.

10. According to Defendants the single use Shapematch Cutting Guides are designed and manufactured from patient specific 3D imaging data that is derived from MRI or CT scans.

11. ShapeMatch Technology utilizes proprietarty 3D imaging software to develop a customized pre-operative surgical plan for each patient. Upon surgeon review and approval the plan is used to develop cutting guides for the individual patient.

12. In April, 2013, the FDA notified health care professional of a Class 1 recall for the product due to a software defect that results in wider cutting ranges. The parameters of the manufactured cutting guides may not meet the surgeon's pre-operative planing parameters entered via the web application. Additionally, Stryker Orthopaedics determined that another software defect resulted in the displayed parameters (e.g., depth of resection angle of cut) not matching the cutting guides produced.

13. These defects may result in serious adverse health consequences, including joint instability, fracture, need for revision surgery and chronic pain and limitations in mobility.

14. At all times material hereto, Defendant developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective ShapeMatch Cutting Guides, either directly or indirectly, to members of the general public within the State of Louisiana, including Plaintiff.

URGENT SAFETY NOTICES AND RECALLS

15. In January, 2013, a Product Notification was issued to all branches, agencies, surgeons and risk managers at affected hospitals, informing them of the problem and risk mitigation factors.

16. On April 10, 2013, Stryker issued an Urgent Medical Device Recall.

17. In the Urgent Medical Device Recall, Defendant went on to describe symptoms and findings nearly identical to those experienced by Plaintiff.

18. Among those symptoms and findings specifically mentioned in the Urgent Medical Device Recall were joint instability, fracture, need for revision surgery and chronic pain and limitations in mobility.

19. The ShapeMatch Cutting Guide has not been available on the market since November, 2012. Stryker is recommending patients who had knee replacement surgery in which ShapeMatch Cutting Guides were used and who are experiencing symptoms to contact their surgeon.

20. Finally, in April, 2013, a Class I recall was issued for all ShapeMatch Cutting

Guides.

PLAINTIFF'S CLAIMS

21. On March 30, 2006, Plaintiff underwent total knee replacement surgery performed by Lafayette General Hospital in Lafayette, Louisiana. Plaintiff's surgeon utilized the ShapeMatch Cutting Guide.

22. Subsequent to her knee replacement, Plaintiff began experiencing significant knee pain and discomfort and joint instability and limitation on mobility.

23. Diagnostic testing has revealed that the knee replacement is misaligned and may need to be replaced.

24. As a direct and proximate result of Defendant placing the ShapeMatch Cutting Guide in to the stream of commerce, Plaintiff has suffered, and continues to suffer, both injuries and damages including, but not limited to, past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related charges.

THE FEDERAL REQUIREMENTS

25. Federal regulation states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." *See* 21 CFR §7.3(m).

26. The FDA categorized the ShapeMatch Cutting Guide recall as a "Class I" recall. A Class I recall is for a dangerous or defective product that could predictably cause serious health problems or death.

27. Classifying the ShapeMatch Cutting Guide as a "Class I" recall confirms by definition that the devices in question were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

28. Pursuant to federal law, a device is deemed to be adulterated, if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing storage or installation are not in conformity with federal requirements. See 21 U.S.A. §351.

29. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

30. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulerated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of their medical devices may have caused or contributed to death or serious

injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring manufacturers of a medical device to report promptly to FDA any correction or removal of a devise undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.A. § 360(I).

31. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury; (or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR § 803.50.

32. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

33. Pursuant to federal regulations, manufacturers must disclose any reportable MDR

event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events See 21 CFR §803.53.

34. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act cause by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

35. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish

and maintain procedures for implementing corrective actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance. See 21 CFR §820.

36. It is believed that with respect to ShapeMatch Cutting Guide, Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

FIRST CAUSE OF ACTION
(Negligence)

37. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

38. Defendant designed, manufactured, marketed, detailed, and advertised, both to physicians and consumers, that the ShapeMatch Cutting Guide was safe and effective for its intended use - pre-operative alignment for total knee replacement surgery.

39. As a result, Defendant had a duty to perform each of these functions reasonably and with a reasonable and due care for the safety and well-being of patients in whom the devices

would be utilized, including Plaintiff. Defendant failed to reasonably execute these duties.

40. Defendant failed to use reasonable and due care for the safety and well-being of those on whom the ShapeMatch Cutting Guide would be utilized, including Plaintiff, and is therefore negligent in the following respects:

a. Defendant failed to adequately design and manufacture the ShapeMatch Cutting Guide to insure that it would not produce a wider cutting range than intended by the surgeon or ensuring that the displayed parameters matched those intended by the surgeon.

b. Defendant failed to adequately test the ShapeMatch Cutting Guide to insure that it would perform correctly;

c. Defendant failed to conduct anything other than bench testing so that when manufactured and marketed, patients like Plaintiff became, in essence Defendant's first clinical trial;

d. Defendant made affirmative representations that the ShapeMatch Cutting Guide would not misalign before surgery. These representations were false and misleading to both physicians and the consumer, including Plaintiff;

e. Defendant trained its sales force to "detail" the ShapeMatch Cutting Guides utilizing representations that the Defendant knew or should have known were false, creating a mistaken belief in the minds of both surgeons and consumers that

the device was safe for its intended use.

f. Defendant failed to promptly act upon reports of early failure such that the ShapeMatch Cutting Guide continued to be utilized in unknowing patients by surgeons well after it should have been recalled or sales suspended.

41. The above conduct illustrates Defendant's failure to exercise reasonable and appropriate care. It was foreseeable that such negligence would lead to premature device failure as well as severe, permanent, debilitating injury to patients, including Plaintiff.

42. As a direct and proximate result of Defendant's negligence, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

SECOND CAUSE OF ACTION
(Breach of Express Warranty)

43. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

44. Through its public statements, its descriptions of the ShapeMatch Cutting Guide its promises relating to the ShapeMatch Cutting Guide, Defendant expressly warranted, among other things, that the ShapeMatch Cutting Guide was effective and safe for its intended use and would last.

45. These warranties came in the form of (i) publicly-made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to crease a demand for the ShapeMatch Cutting Guide (but which

contained material misrepresentations and utterly failed to warn of the risks of the ShapeMatch Cutting Guide; (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the ShapeMatch Cutting Guide that also downplayed the risks associated with the ShapeMatch Cutting Guide; and, (iv) false and misleading written information supplied by Defendant.

46. Plaintiff further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made part of the record once Plaintiff is afforded the opportunity to conduct discovery.

47. When Defendant made these express warranties, it knew the purpose for which the ShapeMatch Cutting Guide was to be used, and warranted it to be in all respects safe and proper for such purpose.

48. Defendant drafted the documents and/or made statements upon which these warranty claims are based and, in doing so, defined the terms of those warranties.

49. The ShapeMatch Cutting Guides do not conform to Defendant's representations in that the device is safe and instead produces serious and debilitating side effects.

50. As such, the ShapeMatch Cutting Guide did not conform to Defendant's promises, descriptions, or affirmations of fact, and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

51. As a direct and proximate result of the breach of Defendant's warranties, Plaintiff suffers, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

THIRD CAUSE OF ACTION
(Breach of Implied Warranty)

52. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

53. At the time Defendant marketed, sold, and distributed the ShapeMatch Cutting Guide, Defendant knew of the use for which the product was intended and impliedly warranted the product to be of merchantable quality, safe, fit and effective for such use.

54. Defendant knew, or had reason to know, that Plaintiff and her physicians would rely on the Defendant's judgment and skill in providing the ShapeMatch Cutting Guide for the intended use.

55. Plaintiff and her physicians reasonably relied upon the skill and judgment of Defendant as to whether the ShapeMatch Cutting Guide was of merchantable quality, safe, fit, and effective for its intended use.

56. Contrary to such implied warranty, ShapeMatch Cutting Guide was not of merchantable quality, nor safe or fit or effective for its intended use, because the product was, and is unreasonably dangerous, defective, unfit and ineffective for the ordinary purposes for which the ShapeMatch Cutting Guide was used.

57. As a direct and proximate result of Defendant's breach of its implied warranty, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

FOURTH CAUSE OF ACTION
(Strict Liability - Failure to Warn)

58. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

59. The ShapeMatch Cutting Guide utilized on Plaintiff contained no warnings, or in the alternative, contained inadequate warnings, as to the risk that the produce could cause significant knee misalignment.

60. The warnings that accompanied the ShapeMatch Cutting Guide failed to provide the level of information that an ordinary consumer would expect when using the product in a manner reasonably foreseeable to Defendant.

61. Had Plaintiff received a proper or adequate warning as to the risks associated with the ShapeMatch Cutting Guide, Plaintiff would not have used the product.

62. Had Plaintiff's surgeon receive a proper or adequate warning as to the risks associated with using the ShapeMatch Cutting Guide, he would not have recommended the device, would have used an alternative device; or, at a minimum, would have provided Plaintiff with an adequate warning and obtained informed consent.

63. As a direct and proximate result of Defendant's failure to warn of these dangers,

Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

64. Defendant is strictly liable for Plaintiff's injuries, damages and losses.

FIFTH CAUSE OF ACTION
(Strict Liability - Design Defect)

65. Plaintiff incorporates by reference all preceding paragraphs as is fully set forth herein and further alleges as follows:

66. Defendant's ShapeMatch Cutting Guide is designed in such a way that, when used as intended, it causes serious, permanent, and devastating damage to patients. The damage and mechanism of injury have been previously described herein.

67. Defendant's ShapeMatch Cutting Guide does not perform as safely as an ordinary consumer would expect when used as intended, or in a manner reasonably foreseeable to Defendant.

68. The risks of using Defendant's ShapeMatch Cutting Guide outweigh the benefits of using the devices.

69. Defendant knew or should have known of the defective nature of its ShapeMatch Cutting Guide, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by its products.

70. As a direct and proximate result of the ShapeMatch Cutting Guide's defective

design, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

71. Defendant is strictly liable for Plaintiff's injuries, damages and losses.

SIXTH CAUSE OF ACTION
(Strict Liability - Manufacturing Defect)

72. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

73. The ShapeMatch Cutting Guide system utilized on Plaintiff failed, causing Plaintiff to possibly undergo complicated surgery to replace the medical device within a short period of time after the original date of implantation. These "revision" surgeries are technically much more difficult than the original surgery, even for skilled orthopedic surgeons, and involve a very long, difficult recovery process.

74. The ShapeMatch Cutting Guide utilized in Plaintiff's surgery contained a manufacturing defect in that the ShapeMatch Cutting Guide utilized in Plaintiff departed from its intended design and became more dangerous.

75. As a direct and proximate result of Defendant's manufacturing defect, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

76. Defendant is strictly liable for Plaintiff's injuries, damages and losses.

SEVENTH CAUSE OF ACTION
(Strict Liability - Failure to Adequately Test)

77. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

78. Defendant advised consumers and the medical community that ShapeMatch Cutting Guide was safe for use in humans. Defendant failed to adequately test its products for use in knee replacement.

79. Had Defendant adequately tested the safety of ShapeMatch Cutting Guide and disclosed those results to the medical community or to the public, Plaintiff would not have used the ShapeMatch Cutting Guide for her total knee replacement.

80. As a direct and proximate result of Defendant's failure to adequately test its product, Plaintiff has suffered the conditions, injuries and damages set forth above.

81. Defendant is strictly liable for Plaintiff's injuries, damages and losses.

EIGHTH CAUSE OF ACTION
(PUNITIVE DAMAGES)

82. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

83. The conduct of Defendant, as set forth hereinabove, was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendant acted only out

of self interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff. Accordingly, punitive damages should be imposed against Defendant to punish and deter Defendant from repeating or continuing such unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays:

(a) That process issue according to law;

(b) That Defendant be served with a copy of the Plaintiff's Complaint and show cause why the prayers for relief requested by Plaintiff herein should not be granted;

(c) That Plaintiff be granted a **trial by jury** in this matter;

(d) That the Court enter a judgment against Defendant for all general and compensatory damages allowable to Plaintiff;

(e) That the court enter a judgment against Defendant for all special damages allowable to Plaintiff;

(f) That the Court enter a judgment against Defendant serving to award Plaintiff punitive damages;

(g) That the Court enter a judgment against Defendant for all other relief sought by Plaintiff under this Complaint;

(h) That the costs of this action be cast upon Defendant; and

(i) That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

MICHAEL HINGLE & ASSOCIATES, LLC

/s/ Bryan A. Pfleeger

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PLEASE SERVE:

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STRYKER SALES CORPORATION
through its registered agent for service of process:
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